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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,664	07/02/2003	Tomihisa Kato	049400-5025	2014
9629	7590	12/16/2004		
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER KASZTEJNA, MATTHEW JOHN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,664

Applicant(s)

KATO ET AL.

Examiner

Matthew J Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/2/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/2/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **In regards to claim 4**, the first sentence should read "according to any one of claims 1 to 3". **In regards to claims 7-11**, it is unclear if applicant is claiming a wire-stranded hollow coil body, a medical endoscope having a cloak tube, a medical endoscope treating tool having a coil sheath, a medical endoscope treating tool having a manipulating sheath portion or a pressure sensor type medical guide wire.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 6,589,227 to Klint.

In regards to claim 1, Klint discloses a wire-stranded hollow coil body 1 comprising a multitude of coil line elements 5 stranded along a predetermined circular line to form a flexible linear tube having a central axial hollow portion, whereby the

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flexible linear tube is stranded under a strand-turn resistant load and heat treated to remove a residual stress upon formation so as to provide a high rotation-following capability and a high straightness (see Col. 6, Lines 20-39).

In regards to claim 2, Klint discloses a wire-stranded hollow coil body wherein the flexible linear tube 1 is lengthwisely divided into pluralistic sections, each of which has different number of strand turns (see Col. 11, Lines 31-39).

In regards to claim 4, Klint discloses a wire-stranded hollow coil body wherein an outer surface of said flexible linear tube is ground in concentric relationship with said predetermined circular line (see Col. 6, Lines 40-53).

In regards to claim 5, Klint discloses a wire-stranded hollow coil body wherein an outer surface of the flexible linear tube is ground by an electrolytic polishing in concentric relationship with said predetermined circular line (see Col. 7, Lines 32-40).

In regards to claim 6, Klint discloses a wire-stranded hollow coil body wherein the coil line elements are austenitic stainless steel (see Col. 5, Line 66 – Col. 6, Line 2).

In regards to claim 7-11, Klint discloses a wire-stranded hollow coil body device which may be a catheter or may be one or more components of a delivery system for endovascular devices (see Col. 3, Lines 18-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,589,227 to Klint in view of U.S. Patent Application Publication No. 2003/0069522 to Jacobsen et al.

In regards to claim 3, Klint discloses a method of making a wire-stranded hollow coil body and is heat treated to remove a residual stress upon formation but is silent with respect to the "flexible linear tube is lengthwisely divided into pluralistic sections, each of which has residual stresses removed in different degrees." Jacobsen et al. teaches of an analogous medical device wherein the thin areas of both the grooved tube (e.g. 4115) and the coil/braid supported structures can be deformed by heat and internal pressure to give a more flexible structure similar to a bellows as shown in FIG. 43 and therefore it is shown that heat treatment effect the flexibility of a coil structure. It would have been obvious to one skilled in the art the time the invention was made to have a coil body with a plurality of sections wherein the residual stresses are removed in different degrees in the apparatus of Klint in order to provide a coil tube which has varying degrees of flexibility over its entire length as taught by Jacobsen et al. and is well-known in the art.

4. Claims 12-14 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,589,227 to Klint in view of U.S. Patent No. 5,932,035 to Koger et al.

In regards to claims 12-14, Klint discloses a method of making a wire-stranded hollow coil body comprising a multitude of coil line elements stranded along a predetermined circular line to form a flexible linear tube having a central axial hollow portion but is silent with respect to a method which involves heat treating by electrically

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conducting between the rotationally active chuck and the fixture. Koger et al. teaches of an analogous device and a production method thereof wherein a nitinol wire 44 is drawn from a supply roll 80 through feed rollers 82, and then passes through winding points 84, a pair of which bend the wire into a coil 86. The winding points are made of a very hard substance, such as steel, that is not subject to wear. A heating stage 88 heats the coil coming off the winding points, making wire 44 superelastic. The coil then slides onto a mandrel 90. After the superelastic coil unwinds off the mandrel, it springs back to its initial shape before being wound on a take-up reel 92. Furthermore, Koger et al. teach of another method of manufacture of the coil, wherein wire 44 winds off a supply roll 80 to feed rollers 82. The wire is then pulled onto a rotating die 100 in the form of a screw with a central mandrel. A forming heater 88 heats the wire wound onto the mandrel as the die rotates. Mandrel 90 holds wound coil 86 as it cools, and a take-up reel 92 takes up the coil as it winds off mandrel 90 (see Col. 6, Lines 23-53). It would have been obvious to one skilled in the art to use a production method involving heat treatment of the wire in the production of the device of Klint in order to produce a wire-stranded wire wherein kinks are much less likely to form in the drive shaft and a wire which is more resistant to mishandling, as taught by Koger et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 4,932,419 to de Toledo.

U.S. Patent No. 5,373,619 to Fleischhacker et al.

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U.S. Patent No. 5,376,083 to Mische

U.S. Patent No. 5,840,046 to Deem

U.S. Patent No. 5,984,877 to Fleischhacker, Jr.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK

12/9/04



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700